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| 10/518,752 | 07/01/2005 | Katayoon Dehesh | 16518.156 | 8071 |

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| EXAMINER |
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MCELWAIN, ELIZABETH F

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| ART UNIT | PAPER NUMBER |
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1638

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02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,752

Applicant(s)

DEHESH ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,12,13 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-11 and 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/4/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed November 5, 2007 has been entered.

Election/Restrictions

1. Applicant's election without traverse of Group XV, claims 1-3, 6-11 and 14-29 to the extent the claims are drawn to SEQ ID NO: 2 in the reply filed on November 5, 2007 is acknowledged

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 27 is indefinite in the recitation of "at least partially reducing the level of a transcript", given that it is unclear how this differs from "reducing the level of a transcript". This phrase does not clearly set forth the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to soybean plants and seeds transformed with at least a portion of a FATB thioesterase of SEQ ID NO: 2 or a sequence 90% identical to SEQ ID NO: 2, and wherein the soybean plant or seed has reduced levels of palmitic or stearic acid relative to a nontransformed plant. Claims are also drawn to plants and seeds produced by transforming a soybean plant with at least a portion of a FATB thioesterase of SEQ ID NO: 2 or a sequence 90% identical to SEQ ID NO: 2; and a second set of DNA sequences encoding one or more of a beta-ketacyl-ACP synthase I, a beta-ketacyl-ACP synthase IV and a delta-9 desaturase. However, the specification does not disclose any soybean seeds transformed with said constructs and the specification does not disclose any soybean plants having reduced levels of either palmitic or stearic acid relative to a nontransformed plant.

De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N).

Voelker et al (Annual Review of Plant Physiology and Plant Molecular Biology 52: 335-361, 2001) teach the complexity of plant lipid biosynthesis and the uncertainty of the resultant seed fatty acid composition when transforming plant species with heterologous genes (see page 345, the third full paragraph, for example). Voelker et al teach that there are “many hundreds of

different fatty acids found in natural plant oils that are mostly produced as a result of changes in a few amino acids of a handful of lipid biosynthetic genes” (see page 354, the last paragraph) and that plants transformed with fatty acid biosynthesis genes from heterologous plant species do not always have fatty acid profiles that correspond to those of the plant from which the gene was cloned (see page 341, the first full paragraph). For example, soybean embryos transformed with a borage delta-6 desaturase produce gamma-linolenic acid, but transformed canola seeds do not.

Voelker et al also teach that some plants have enzymes with specialized activities (page 344, the first full paragraph). However, the availability of enzyme substrates also has an effect on the resultant fatty acid profile of a given plant species (see page 343, the third to last full sentence). In addition, Voelker et al teach the high degree of sequence similarity between some fatty acid biosynthesis genes, such as fatty acid desaturases, wherein as few as two amino acids can result in a change in substrate specificity and as few as five amino acids can produce changes in both substrate and regiospecificities of an acyl-ACP desaturase (see page 345, the first full paragraph). Furthermore, Voelker et al teaches that the hydroxylase enzyme from *Lesquerella* is bifunctional in that it has some omega-6 desaturase activity in addition to hydroxylase activity and that small differences in active site geometry are responsible for the different functional activities (see page 347, the last full paragraph). There are also FAD2 related sequences that function as epoxxygenases and acetylenases (see pages 347-348, the paragraph bridging the pages).

Voelker et al also teach uncertainty with regard to the distribution of membrane and storage lipids in plants transformed with heterologous fatty acid biosynthesis genes (see the third full paragraph of page 351 and page 352, the second full paragraph). There are also reports of

altered plant morphology and organelle structure in transgenic plants having modified fatty acid biosynthesis (page 353, the second full paragraph).

More specifically, Voelker et al teach that transformation of a plant with a FATB thioesterase coding sequence resulted in increased levels of the saturated fatty acid, laurate (the paragraph bridging pages 342-343) as opposed to a decrease in saturated fatty acids, which is claimed. In addition, Topfer et al (Science 268: 681-685, 5 May 1995 in IDS) teach that overexpression of a thioesterase produced a transgenic line have increased levels of stearic acid (page 682, the last full paragraph). Topfer et al also teach the variability of genes in the thioesterase gene family. *Cuphea* was found to have at least four different genes encoding FATB thioesterases and that transformation of plants with two of these genes resulted in distinct altered fatty acid profiles, wherein one gene produced seeds having caprylic acid and the other produced seeds having myristic acid.

Futhermore, claims are broadly drawn to a soybean plant or seed that has been transformed with at least 25 nucleotides of a nucleic acid that has at least 90% identity to SEQ ID NO: 2, and said plants or seeds optionally transformed with additional genes. However, the claims either provide no limitation with regard to an altered phenotype of the transgenic plant or the claims provide several different phenotypes for the claimed soybean plants and seeds (reduced palmitic acid or reduced stearic acid or increased oleic acid). The specification does not provide guidance with regard to selecting for transformed plants and seeds from the plants produced by transformation with any of the vast multitude of possible constructs that are claimed. Given the lack of guidance with regard to identifying and selecting for phenotypic traits, one skilled in the art would not know how to use the claimed soybean plants and seeds. In

addition, there is not guidance provided with regard to extraction and analysis of fatty acids from whole plants, as opposed to seeds.

The modification of plant lipid composition to produce seeds having modified fatty acid levels of particular fatty acids by transforming a plant with one or more nucleic acids that encode fatty acid biosynthesis genes is highly unpredictable. Given the high level of unpredictability of modifying plant fatty acid composition by transforming plants with fatty acid biosynthetic genes, as taught by DeLuca, Voelker et al and Topfer et al; given the lack of working examples of soybean seeds transformed with any of the disclosed and claimed constructs, and the lack of working examples of soybean seeds having reduced levels of palmitic acid or stearic acid, or having increased levels of oleic acid; given the breadth of the claims which encompass soybean seeds transformed with an unlimited number of possible gene constructs comprising any portion of at least 25 contiguous nucleotides of SEQ ID NO: 2 or sequences 90% identical thereto, and optionally further comprising any number of additional genes encoding beta-ketacyl-ACP synthase I, a beta-ketacyl-ACP synthase IV and a delta-9 desaturases from unspecified species; and given the absence of guidance with regard to choosing from this multitude of constructs to produce and select for the claimed soybean seeds; and the absence of guidance with regard to using the transformed plants and seeds; it would require undue experimentation by one skilled in the art to make and use the invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 7, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehesh et al (Plant J 15(3): 383-390, 1998) taken with Shoemaker et al (Database Accession AW568268, 3 Dec 2001).

9. The claims are drawn to recombinant nucleic acids comprising at least 25, 50 or 100 contiguous nucleotides of a FATB thioesterase of SEQ ID NO: 2 or of a sequence 90% identical to SEQ ID NO: 2 and operably linked to a promoter that functions in a plant cell for expression in the seed. Claims are also drawn to a recombinant nucleic acid comprising at least 25 nucleotides of the FATB thioesterase of SEQ ID NO: 2 or a sequence 90% identical to SEQ ID NO: 2; and a second set of DNA sequences encoding one or more of a beta-ketacyl-ACP synthase I, a beta-ketacyl-ACP synthase IV and a delta-9 desaturase.

10. Dehesh et al teach a recombinant nucleic acid comprising a napin seed-specific promoter operably linked to a FATB thioesterase gene sequence and said construct further comprising a coding sequence for a KAS IV gene (see page 389, the first column).

11. Dehesh et al do not specifically teach SEQ ID NO: 2.

12. Shoemaker et al teach SEQ ID NO: 2, which is identified as an acyl-ACP thioesterase.

13. Given the recognition of those of ordinary skill in the art of having the construct of Dehesh et al comprising a plant seed-specific promoter operably linked to a plant FATB sequence and optionally to a second fatty acid biosynthesis genes, such as KAS IV for modulating fatty acid levels when transformed into a plant, it would have been obvious to modify this construct by substituting other known thioesterase coding sequences, such as that of SEQ ID NO: 2, as taught by Shoemaker et al. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

14. Claims 3, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehesh et al and Shoemaker et al as applied to claims 1, 2, 7, 8, 10 and 11 above, and further in view of applicants' admitted state of the prior art.

15. Dehesh et al taken with Shoemaker et al teach a recombinant construct comprising a plant seed-specific promoter operably linked to a plant FATB sequence of SEQ ID NO: 2 and optionally to a second fatty acid biosynthesis genes, such as KAS IV for modulating fatty acid levels when transformed into a plant.

16. Dehesh et al taken with Shoemaker et al do not specifically teach using a 7S promoter, that the nucleic acid is capable of expressing dsRNA or the construct additionally comprising a delta-9 desaturase coding sequence.

17. Applicants' admitted state of the prior art teaches that delta-9 desaturase genes were known (see page 9), and 7S seed specific promoters were known (page 24) and the use of double stranded RNA was known for disruption of gene expression (page 29).

18. Given the recognition of those of ordinary skill in the art of having the construct of Dehesh et al taken with Shoemaker et al for modulating fatty acid levels in a plant, it would have been obvious to modify this construct by substituting other known sequences as provided by applicants' admitted state of the prior art, such as the 7S promoter, or other known fatty acid biosynthesis genes, such as the delta-9 desaturase gene for the modulation of fatty acid levels. In addition, the use of a sequence that is capable of producing dsRNA would be optimization of process parameters and was taught in the prior art, as set forth by applicants in the specification. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Elizabeth F. McElwain
Primary Examiner
Art Unit 1638

EFM